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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,455	04/01/2004	Cristina E. Davis	DPL-048	1601

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EXAMINER

MALLARI, PATRICIA C

ART UNIT PAPER NUMBER

3736

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,455	DAVIS ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 16-20, 26 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 21-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/28/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicants' election with traverse of Group I and Species A, G, and I in the reply filed on 1/9/06 is acknowledged. The applicants' traversal of Group I the election requirement of Groups I-II is found persuasive. The applicants' traversal of Species A-C, D-g, and H-I is not found persuasive. The traversal is on the ground(s) that a search for publications relating to any of the species would reveal publications relating to any of the other species and thus would not impose a serious burden on the Examiner. This is not found persuasive because a search for one of the species would not necessarily reveal all publication relating to any one of the other species, therefore requiring separate search of the different species, which would require a serious burden on the examiner. Claims 16-20 and 26 remain withdrawn from examination.

The requirement is still deemed proper and is therefore made FINAL.

Additionally, restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-27, drawn to a method for breath analysis, classified in class 600, subclass 529.
- II. Claims 28-30, drawn to an asymmetric field ion mobility spectrometer, classified in class 600, subclass 532.

Regarding Invention I, although the preambles of each claim states, "A system for breath analysis" or "The system", it is clear that the actual invention is a method since

the content of the body of claim 1 is directed towards method steps rather than elements of an apparatus or system.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, such as analysis of a non-respiratory gas. The limitation "for breath analysis" or "for identification of ion species in breath sample" is merely "intended use" and is limiting only insofar as requiring the apparatus to be capable of such analysis, but a reference or invention being so capable does not necessarily have to disclose such use.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Beloborodov on March 21, 2006 a provisional election was made with traverse to prosecute the invention of I, claims 1-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 1-27 are objected to because of the following informalities:

On line 1 of each claim "system" should be replaced with "method".

On line 1 of claim 6, "further comprising" should be replaced with "where the spectrometer further comprises".

On line 1 of claim 8, "further comprising" should be replaced with "wherein the spectrometer further comprises".

On line 2 of claim 8, "a-channel" should be replaced with "a channel".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-11, 13-15, 21-25, and 27 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent No. 5,425,374 to Ueda et al. in view of US Patent No. 6,512,224 to Miller et al. Ueda teaches a method for breath analysis wherein a breath sample is provided to a gas analysis device, wherein the gas analysis device may be an ion mobility spectrometer (col. 4, lines 14-28; col. 10, lines 43-66; col. 12, line 49-col. 13, line 2 of Ueda). Ueda fails to describe the ion mobility spectrometer in full detail.

However, Miller teaches an asymmetric field ion mobility spectrometer comprising an ionization source 236 for ionizing the breath sample and creating ions, an analytical gap 232 enclosed by a housing 234, an ion filter 240 disposed in the analytical gap 232 downstream from the ionization source 236 and including electrodes 246, 248 on an inside surface of the housing 234 for creating an asymmetric electric field to filter the ions, an ion flow generator 250 including electrodes 260-267 proximate but insulated with respect to the ion filter electrodes 246, 248 for creating an electric field transverse to the asymmetric electric field for propelling ions through the asymmetric electric field, and an ion detector 270 for sensing ions not filtered by the ion filter 240 (fig. 14; col. 8, line 30-col. 9, line 10 of Miller). Therefore, it would have been obvious to use the ion mobility spectrometer of Miller in the method of Ueda, since Ueda teaches using an ion mobility spectrometer, and Miller describes an appropriate such spectrometer. It would similarly have been obvious to use the spectrometer of Miller in the method of Ueda to minimize the power required for the spectrometer (col. 8, lines 15-39; col. 9, lines 1-5 of Miller).

Regarding claim 3, the breath sample is introduced into the spectrometer (Col. 12, lines 58-65 of Ueda; fig. 14 of Miller).

Regarding claim 5, a predetermined volume of breath sample may be introduced into the spectrometer (col. 11, lines 17-26; col. 12, lines 54-56 of Ueda).

Regarding claim 6, a pressure source may be used to introduce the breath sample into the spectrometer (fig. 1; col. 11, lines 7-16 of Ueda).

Regarding claims 7-9, the breath sample is exhaled into the spectrometer (col. 11, lines 14-16; col. 12, lines 49-63 of Ueda). With further regard to claim 8, a channel is provided, the channel being adapted to introduce the exhaled breath sample into the spectrometer (col. 11, lines 14-16; col. 12, lines 52-65 of Ueda). Regarding claim 9, the channel comprises a mouthpiece (col. 4, lines 50-54; col. 11, lines 14-16; col. 12, lines 52-63 of Ueda).

Regarding claims 10 and 11, the breath sample is contained in a collection vessel (col. 11, lines 17-26; col. 12, lines 49-59 of Ueda). With further regard to claim 11, a conduit is provided, adapted to introduce the breath sample collected in the collection vessel, into the spectrometer (col. 11, lines 10-26 of Ueda).

Regarding claim 13, intermediate analytical separation of the breath sample is provided prior to introducing the breath sample to the spectrometer (col. 11, lines 10-14; col. 12, lines 12-20; col. 12, lines 54-65 of Ueda).

Regarding claim 14, providing a breath sample comprises breathing according to a standard protocol prior to providing the breath sample (col. 7, lines 63-67 of Ueda).

Regarding claim 15, the breath sample may be taken from a patient suspected to have a metabolic disease or organ dysfunction (col. 9, line 1-col. 10, line 39 of Ueda), wherein it is inherent that a person would only be tested for a disease if he or she were suspected to have such disease.

Regarding claim 21, the ion detector is adapted to sense ions indicative of at least bacterial infection, viral infection, fungal infection, yeast infection, infectious disease agents, response to biowarfare agents, or emerging infectious disease agents, wherein, in particular, ozostomia may be due to bacterial infection (col. 9, line 1- col. 10, line 39 of Ueda).

Regarding claims 22 and 24, the spectrometer may be hand held or is fieldable, wherein the term "fieldable" is taken to mean "portable" (col. 3, lines 23-25 of Ueda; col. 6, lines 47-48 of Miller).

Regarding claim 23, the spectrometer is adapted to have an independent power supply (col. 6, lines 24-27 of Ueda).

Regarding claims 25 and 27, a data collector 61 is provided to collect the ion sensed by the ion detector and the collected data is evaluated for a pattern (fig. 1; col. 7, lines 30-40 of Ueda). With further regard to claim 27, the data collector 61 is disposed on the housing of the spectrometer (figs. 5-7 of Miller).

Claims 2, 4, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda in view of Miller, as applied to claims 1, 3, 5-11, 13-15, 21-25, and 27 above, and further in view of US Patent No. 6,010,459 to Silkoff et al. Ueda, as modified, lacks

providing a constant rate of breath expiration or providing a signal to a user that the breath sample rate is constant. However, Silkoff teaches a method for measuring components of exhaled breath of a subject wherein a constant rate of breath expiration is provided when providing the breath sample, and such constant rate is ensured by providing a signal to a user that the breath sample rate is constant (col. 4, lines 1-17 of Silkoff). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Silkoff with that of Ueda, as modified by Miller, in order to eliminate complications caused by an uncontrolled expiratory flow rate in the measurement and evaluation of breath samples (col. 3, lines 11-29 of Silkoff).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda in view of Miller, as applied to claims 1, 3, 5-11, 13-15, 21-25, and 27 above, and further in view of US Patent No. 4,579,826 to Bolton et al. Ueda, as modified, teaches collecting breath in a syringe and then providing the collected breath from the syringe to the spectrometer (col. 11, lines 16-26 of Ueda) but fails to describe providing the breath from the syringe in detail. However, Bolton teaches breath collection into a tube or syringe, wherein the collected breath is provided from the tube or syringe at a constant rate (col. 2, line 36-col. 3, line 25; col. 7, lines 49-62 of Bolton). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the use of the syringe or tube of Bolton with the method of Ueda, as modified by Miller, since Ueda, as modified, teaches providing the breath from a syringe to the spectrometer, and Bolton teaches an appropriate method for doing so.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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